Jury Trial Requested

ν.

Plaintiff

Racing Optics, Inc.,

a California Corporation,

Defendants

U.S. DISTRICT COURT IN THE UNITED STATES COUNTRITHERN DISTRICT OF TEXAS OF TEXASETTED FOR THE NORTHERN DISTRIC **Dallas Division** AUG 2 6 2009 Reaux Medical Industries, LLC 999999999999 CLERK, U.S. DISTRICT a Texas Limited Liability Company Deputy Civil Action No. -09CV1582-M Stryker Corporation, a Michigan Corporation,

PLAINTIFF'S ORIGINAL VERIFIED COMPLAINT

NOW COMES Plaintiff, Reaux Medical Industries, LLC (hereafter referred to as "Reaux" or "Plaintiff") for its claims against Defendants and alleges as follows:

THE PARTIES

- Plaintiff, Reaux Medical Industries, LLC, is a Texas Limited Liability Company with a 1. principal place of business at 710 Rock Hill Drive, Red Oak, Texas.
- 2. Defendant, Stryker Corporation, is a Michigan corporation with a principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan, and is doing business in the State of Texas directly or indirectly.
- 3. Racing Optics, Inc. is a California corporation with a principal place of business at 6100 North Hollywood Boulevard, Suite 106, Las Vegas, Nevada (a prior principal place of business at 1218 Puerta Del Sol, San Clemente, California), and is doing business in the State of Texas directly or indirectly.

JURISDICTION AND VENUE

- 4. This is an action arising under the United States Patent Laws, Title 35 of the United States Code. There is complete diversity of citizenship between the Plaintiff and every Defendant, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.
- 5. The court has personal jurisdiction over Defendants because each Defendant has purposefully availed itself of the benefits of the forum state. The Defendants have conducted and continues to conduct business in the State of Texas, and it is believed in this judicial district, directly or indirectly relating to the controversy at issue.
- 6. The court has subject matter jurisdiction under 28 U.S.C. §§1331, 1332, and 1338. Venue properly lies in the Northern District of Texas, Dallas Division, pursuant to 28 U.S.C. §§1391(b)(c) and § 1400(b).

FACTUAL BACKGROUND

- 7. Mr. Brian K. Reaux is the sole inventor of the invention described and claimed in United States Patent Number 7,540,039 (hereinafter "the '039 Patent"), and Mr. Reaux has assigned all right, title and interest to the '039 Patent (as well as all claims and causes of action against the Defendants) to the Plaintiff Reaux Medical Industries, LLC. The assignment of record has been filed with the U.S. Patent & Trademark Office Assignments Branch at Reel/Frame No. 023107/0229-230.
- 8. The Reaux '039 Patent covers a method of making a face and eye covering device that includes steps of combining an eye shield with an air permeable face cover, where the eye shield has at least two transparent laminated layers of flexible material (a lens and at least one protector

removed from the other.

film of lesser thickness than lens) that are releasable so that one of the layers may be selectively

- 9. Defendant Stryker Corporation imports, ships, manufactures and/or sells to customers in this judicial district and elsewhere a T5 HYTREL® Zipper Toga w/Peel Away Face Shield for use with the Stryker Steri-Shield® System, Stryker Ref. No. 400-851-100 and other products that are made using the claims of the Reaux '039 Patent.
- 10. This and other infringing Stryker products are made according to the claimed invention with the assistance and information of Defendant Racing Optics, Inc., which was provided based on information acquired from Mr. Reaux in the State of Texas.
- 11. Defendant Racing Optics, Inc. and its representatives acquired information from sources in the State of Texas regarding the appropriate specifications, configurations of the laminated face shield, and the steps of constructing the face shield as covered by the Reaux '039 Patent based on direct communications with the inventor, Brian Reaux, and his representatives located in the State of Texas while the Reaux '039 Patent was pending at the U.S. Patent & Trademark Office.
- 12. Based on information and belief, prior to the earliest communications between the inventor Brian Reaux (and his representatives) and Racing Optics, Inc. (and its representatives), Racing Optics did not know how to produce an optical face shield products that could be used in medical procedures, did not contemplate producing or assisting others with the production of an optical face shield products that could be used in medical procedures, and did not produce, sell, consult with anyone regarding, and/or assist others with production of an optical face shield products that could be used in medical procedures.

- 13. Based on information and belief, none of the Defendants produced, manufactured or sold an optical face shield made by the method claimed in the '039 Patent prior to direct communications between the inventor Brian Reaux (and his representatives) and Racing Optics, Inc. (and its representatives), which only began after the earliest effective filing date of the Reaux '039 Patent.
- 14. Based on information and belief, the Defendants began to collaborate regarding the production, manufacture and sale of an optical face shield made using the method claimed in the '039 Patent only after, and as a direct result of, the direct communications between the inventor Brian Reaux (his representatives) and Racing Optics, Inc. (and its representatives), which only began after the earliest effective filing date of the Reaux '039 Patent.

COUNT I – INFRINGEMENT OF U.S. PATENT 7,540,039

- 15. Plaintiff repeats the allegations of paragraphs 1-14 as if fully set forth herein.
- 16. U.S. Patent 7,540,039, entitled "Face and Eye Covering Device," issued on June 2, 2009 ("the '039 Patent"). A copy of the '039 Patent is attached as Exhibit 1 to this Complaint.
- 17. Mr. Brian K. Reaux is sole inventor of the '039 Patent, and he assigned all right, title, and interest in and to the '039 Patent to the Plaintiff Reaux Medical Industries, LLC.
- 18. Defendants have infringed, and continue to infringe, induce others to infringe, and/or contribute to the infringement of the '039 Patent.
- 19. Defendants infringe the '039 Patent, inter alia, by importing into the United States, offering to sell, selling products, having product sold by, and/or using products made by (as well as assisting others in such activities) the steps covered by the claims of the Reaux '039 Patent, such as (by way of example) the T5 HYTREL® Zipper Toga w/Peel Away Face Shield in the

Stryker Steri-Shield® System, Stryker Ref. No. 400-851-100. A product label for the identified infringing Stryker product is attached as Exhibit 2.

- 20. Defendants infringe the '039 Patent, inter alia, by offering to sell or selling within the United States and/or importing into the United States a material or apparatus for use in practicing a patented process, wherein said material or apparatus constitutes a material part of the invention and Defendants knew the material or apparatus was especially made or adapted for use in an infringement of the '039 Patent, including (by way of example) materials and apparatus involved with the T5 HYTREL® Zipper Toga w/Peel Away Face Shield in the Stryker Steri-Shield® System, Stryker Ref. No. 400-851-100.
- 21. The identified Stryker product and other infringing products are made by the steps claimed in the '039 Patent by, in cooperation with, or through the involvement and information provided by one or more of the Defendants.
- 22. Defendants infringe the '039 Patent by actively inducing the infringement of the '039 Patent by others.
- 23. A webpage maintained by Stryker Corporation has a photograph of its Sterishield Togas and Face Shields, the webpage having a web address of "www.stryker.com/enus/Solutions/OncologyTreatment/T5PersonalProtectionSystem" and that webpage attached as Exhibit 3.
- 24. The same photograph of the Stryker Sterishield Togas and Face Shield appears on the "home" webpage maintained by Racing Optics and identified as part of its Medical Systems products, the web address being "www.racingoptics.com" and that webpage attached as Exhibit 4, page 1. Stryker Corporation is also identified as a "Partner" of the "Racing Optics product

line" "Partners" which located the Racing Optics webpage, is at "www.racingoptics.com/partners.php" and attached at Exhibit 4, page 2.

- 25. The activities of the Defendants in making, and assisting others with the making, of products covered by the '039 Patent and/or selling products made by the method claimed in the '039 Patent constitutes infringement under the United States Patent laws. The Defendants infringe the '039 Patent, directly or indirectly, by making product, assisting others with that making, selling product made by, and importing product made by the claims in the '039 Patent, including the identified product and other infringing products. .
- 26. The Defendants' acts of infringement of the '039 Patent have caused and will continue to cause immediate and irreparable injury to Plaintiff for which Plaintiff is entitled to injunctive relief under 35 U.S.C. § 283. These Defendants will continue to infringe the '039 Patent unless enjoined by this Court.
- 27. The Defendants acts of infringement of the '039 Patent have caused and will continue to cause injury to Plaintiff for which Plaintiff is entitled to damages and other relief under 35 U.S.C. § 284.
- 28. The Defendants infringement of the Reaux '039 Patent has been and continues to be willful and deliberate, and in flagrant disregard of Plaintiff's rights under the Reaux '039 Patent for which enhanced damages and attorney fees should be awarded under a willful infringement finding and/or a finding of exceptional case.
- 29. Plaintiff seeks and requests recovery of its pre-judgment and post-judgment interests as well as Court costs for the infringement of the Reaux '039 Patent.

COUNT II – MISAPPROPRIATION AND UNFAIR COMPETITION

- 30. Plaintiff repeats the allegations of paragraphs 1-14 as if fully set forth herein.
- 31. Prior to filing for the patent protection disclosed and claimed in the Reaux '039 Patent, Mr. Reaux developed one or more methods for carrying out the claimed invention in the '039 Patent.
- 32. After filing for patent protection (utility and/or provision filings) but before issuance of the Reaux '039 Patent by the U.S. Patent & Trademark Office, Mr. Reaux and/or his representatives disclosed information relating to the design, research and development efforts, and physical dimensions and specifications for a surgical lens product with peel-away laminated sheets to representatives of Racing Optics, Inc., including (but is not limited to) Bart Wilson, President of Racing Optics, Inc.
- 33. Racing Optics, Inc. was notified, and understood, that Mr. Reaux had filed a patent application the covered the Plaintiff's information regarding the methods, design, research and development efforts, and physical dimensions and specifications for the surgical lens product when the information was provided to Racing Optics by Mr. Reaux or his representatives.
- 34. The information regarding the methods, design, research and development efforts, and physical dimensions and specifications for the surgical lens product with peel-away laminated sheets was requested by Racing Optics, Inc.
- 35. While the Reaux '039 Patent was pending at the U.S. Patent & Trademark Office, Defendant Racing Optics, Inc. and its representatives acquired information about Mr. Reaux's methods, design, research and development efforts, and physical dimensions and specifications

for the surgical lens products with peel-away laminated sheets as part of good faith business dealings between the parties.

- 36. Representatives of Defendant Racing Optics approached the other defendant in this matter and conveyed to it Mr. Reaux's information regarding disclosed methods, design, research and development efforts, and physical dimensions and specifications for the surgical lens product with peel-away laminated sheets.
- 37. Representatives of Defendant Racing Optics entered into one or more agreements with the other defendant in this matter to improperly use Mr. Reaux's disclosed information as part of a production of surgical lens products with peel-away laminated sheets.
- 38. Based on information and belief, prior to the earliest communications between the Brian Reaux (and his representatives) and Racing Optics, Inc. (and its representatives), none of the defendants produced, sold, and/or assisted anyone with the production and sale of an optical face shield for use in medical/surgical procedures that was configured or produced using the method or technology developed and disclosed by Mr. Reaux.
- 39. Based on information and belief, none of the Defendants manufactured or sold an optical face shield (or components for use therein) for use in medical/surgical procedures that related in any manner to Mr. Reaux's surgical lens product designs, methods, research and development efforts, and physical dimensions and specifications prior to the direct communications of such information to Racing Optics, Inc.
- 40. Based on information and belief, the Defendants began to collaborate with each other regarding the production, manufacture and sale of an optical face shield (and components for use in same) for use in medical/surgical procedures only after, and as a direct result of, the direct

communications between the Brian Reaux (and his representatives) and Racing Optics, Inc. (and its representatives).

- 41. Defendant Racing Optics, Inc., in collaboration with the other Defendants, has marketed, produced and sold, and assisted others with the marketing, production and sale, of optical face shield products for use in medical/surgical procedures that improperly disclose and use Mr. Reaux's information regarding his surgical lens product.
- 42. Defendant Stryker, in collaboration with Racing Optics, Inc., has marketed and sold an optical face shield for use in medical/surgical procedures that unlawfully duplicates Mr. Reaux's surgical lens product.
- 43. Defendant Racing Optics, Inc. has collaborated with Defendant Stryker to market, sell, produce, and assisted others in such activities, an optical face shield for use in medical/surgical procedures that improperly uses and discloses Mr. Reaux's information regarding the design, research and development efforts, and physical dimensions and specifications as provided to Racing Optics, Inc.
- 44. Defendant Racing Optics, Inc. and/or Defendant Stryker misappropriated the Mr. Reaux's information regarding the design, research and development efforts, and physical dimensions and specifications of Mr. Reaux's surgical lens product.
- 45. Defendant Racing Optics, Inc. and/or Defendant Stryker have gained an unfair advantage in the marketplace by capitalizing on the Mr. Reaux's information regarding the design, research and development efforts, and physical dimensions and specifications of his surgical lens product as provided, directly or indirectly, to the defendants.

- 46. Defendant Racing Optics, Inc. and/or Defendant Stryker have exploited, improperly used, and improperly disclosed Mr. Reaux's information regarding the design, research and development efforts, physical dimensions and specifications of his surgical lens product.
- 47. The Plaintiff has a pecuniary interest in Mr. Reaux's information regarding the methods, design, research and development efforts, physical dimensions and specifications of his surgical lens product and has been assigned all rights to pursue any claims related to the improper use of such information for the time period prior to the issuance of the Reaux '039 Patent.
- 48. The Defendants Racing Optics, Inc. and/or Stryker Corporation have profited from the improper use of Mr. Reaux's information relating to his surgical lens product.
- 49. The improper and unauthorized use, duplication, and copying of the Mr. Reaux's information as to the methods, design, research and development efforts, physical dimensions and specifications of his surgical lens product has damaged Mr. Reaux, the Plaintiff and its prospective business.
- 50. Mr. Reaux and the Plaintiff have been prevented from acquiring lens components for its prospective medical/surgical hood product by one or more of the Defendants, which has damaged the Mr. Reaux and the Plaintiff.
- 51. Defendant Racing Optics, Inc. and/or Defendant Stryker damaged the Plaintiff and its ability to start up a business through its actions, alone or in combination with the other Defendants.
- 52. The Defendants' acts constitute illegal misappropriation and unfair competition under the laws of the State of Texas.

- 53. The Defendants' actions have caused and will continue to cause immediate and irreparable injury to Plaintiff for which Plaintiff is entitled to injunctive relief.
- 54. The Defendants acts have caused and will continue to cause injury to Plaintiff for which Plaintiff is entitled to relief that includes damages, enhanced damages and attorney fees, which should be awarded to the Plaintiff.
- 55. Plaintiff seeks and requests recovery of its pre-judgment and post-judgment interest, as well as Court attorney fees and costs for the Defendants' acts of unfair competition and misappropriation.

WHEREFORE, Plaintiff Reaux Medical Industries, LLC prays for judgment as follows:

- 1. Adjudge U.S. Patent 7,540,039 to be valid and infringed;
- 2. Preliminarily and permanently enjoin Defendants, and any other person or entity in concert or participation with the Defendants, from any infringing activity that is covered by the Reaux '039 Patent and federal patent law protection;
- 3. Adjudge the Defendants to have committed unfair competition and misappropriation in violation of Texas state law;
- 4. Preliminarily and permanently enjoin Defendants, and any other person or entity in concert or participation with the Defendants, from any engaging in any further acts of unfair competition or misappropriation;
- 5. Award the Plaintiff damages suffered as a result of Defendants' acts of patent infringement and/or the Defendants' acts of unfair competition and misappropriation,
- 6. A finding that the infringement was willful and that the damages be increased up to three times the amount found or assessed under 35 U.S.C. § 284;

- 7. A finding that enhanced damages should be awarded for the Defendants' acts of unfair competition and misappropriation;
- 8. A finding that this case is exceptional and an award Plaintiff attorneys' fees under 35 U.S.C. § 285;
- 9. Award the Plaintiff pre-judgment and post-judgment interest in the maximum amount allowed by law;
- 10. Award the Plaintiff costs, expenses, and attorney fees of this action; and,
- 11. Award the Plaintiff such other and further relief as the Court may deem just.

Jury Demand

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted.

Dated: 8/26/2009

D. Scott Hemingway

TX Bar No. 09407880

Eugenia S. Hansen

Hemingway & Hansen, LLP 1717 Main Street, Suite 2500

Dallas, Texas 75225

(214) 292-8301

(214) 739-5209 (fax)

shemingway@hemlaw.org

VERIFICATION

I, Brian K. Reaux, am a citizen of the United States and a resident of the State of Texas. I have read the foregoing Original Verified Complaint and declare under penalty of perjury under the laws of the United States of America that the foregoing factual averments are true and correct to the best of my knowledge and belief.

Brian K. Reaux, for and on behalf of Reaux Medical Industries, LLC

AUG -25-09 Date

EXHIBIT 1



(12) United States Patent Reaux

(10) Patent No.:

US 7,540,039 B2

(45) Date of Patent:

Jun. 2, 2009

(54) FACE AND EYE COVERING DEVICE

(76)	Inventor:	Brian K. Reaux, 710 Rock Hill Dr., Red
		Oak, TX (US) 75154

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 379 days.

(21) Appl. No.: 10/872,034

(22)Filed: Jun. 18, 2004

(65)**Prior Publication Data**

> US 2005/0015860 A1 Jan. 27, 2005

Related U.S. Application Data

- Provisional application No. 60/479,652, filed on Jun. 19, 2003.
- (51) Int. Cl. A42B 1/08

(2006.01)

- 2/206; 2/432; 2/434; 2/438; 128/201.15
- (58) Field of Classification Search 2/424, 2/9, 15, 11, 432, 434, 173, 206, 438; 128/857, 128/201.17, 201.24, 206.19, 201.14, 201.15 See application file for complete search history.

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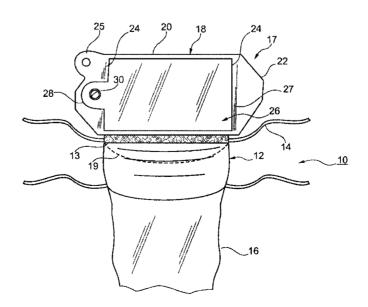
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Primary Examiner—Gary L. Welch Assistant Examiner—Nathan E Durham (74) Attorney, Agent, or Firm-Grady K. Bergen; Griggs Bergen LLP

(57)**ABSTRACT**

A face and eye covering device includes a face cover configured for covering the nose and mouth of a wearer. The face cover is air permeable to allow the passage of air therethrough to facilitate breathing when worn over the wearer's nose or mouth. An eye shield is coupled to the face cover. The eye shield includes a lens and a lens protector releasably coupled to the lens. At least a portion of the lens and lens protector are transparent to allow visual perception therethrough.

15 Claims, 8 Drawing Sheets



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U.S. PATENT DOCUMENTS	6,388,813 B1 5/2002 Wilson et al. 6,461,709 B1 * 10/2002 Janssen et al		
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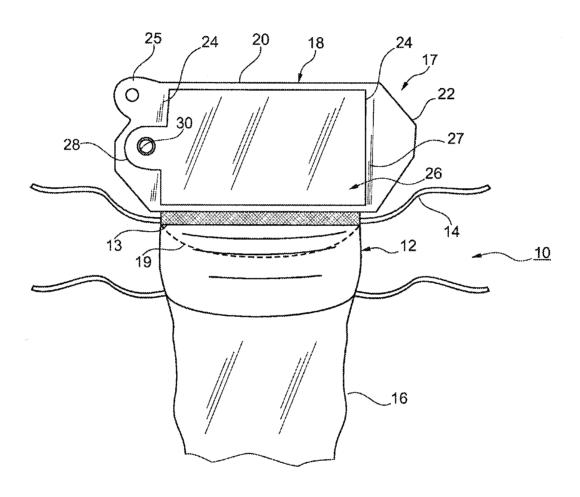


Fig. 1

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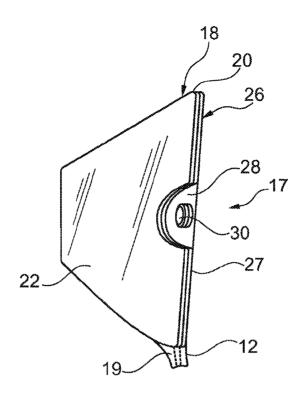


Fig. 2

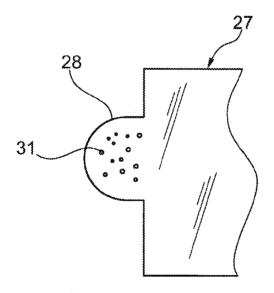


Fig. 3

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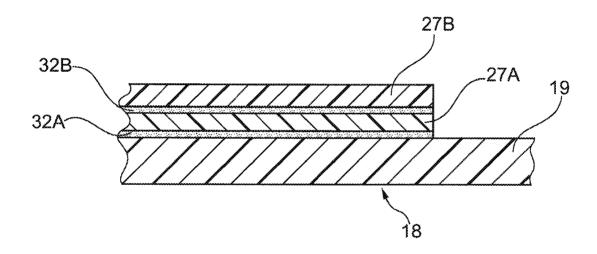


Fig. 4

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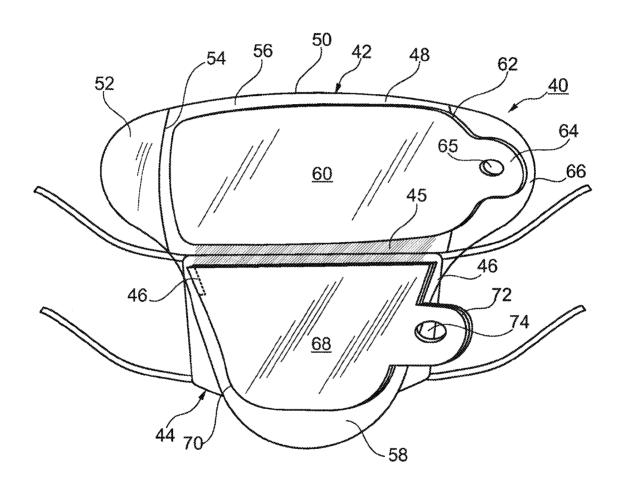


Fig. 5

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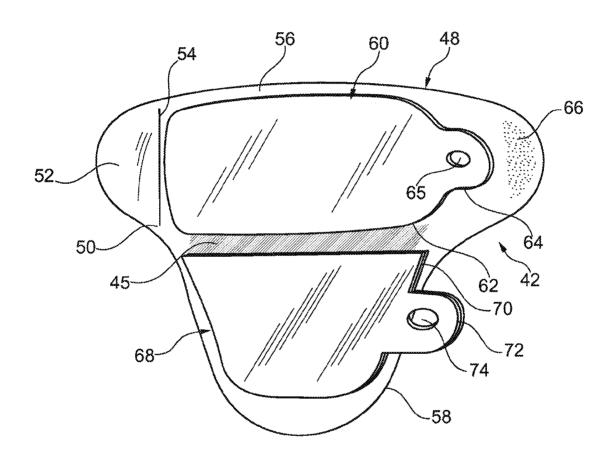


Fig. 6

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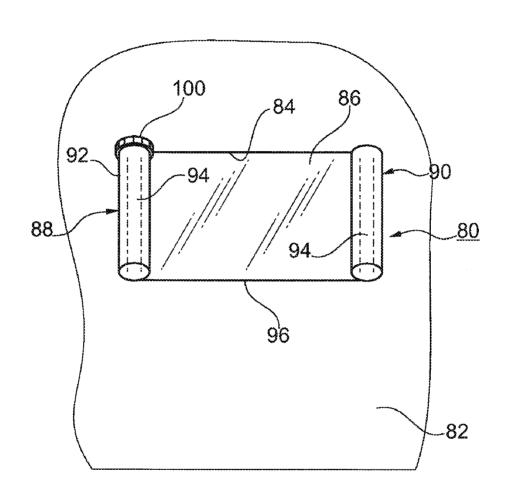
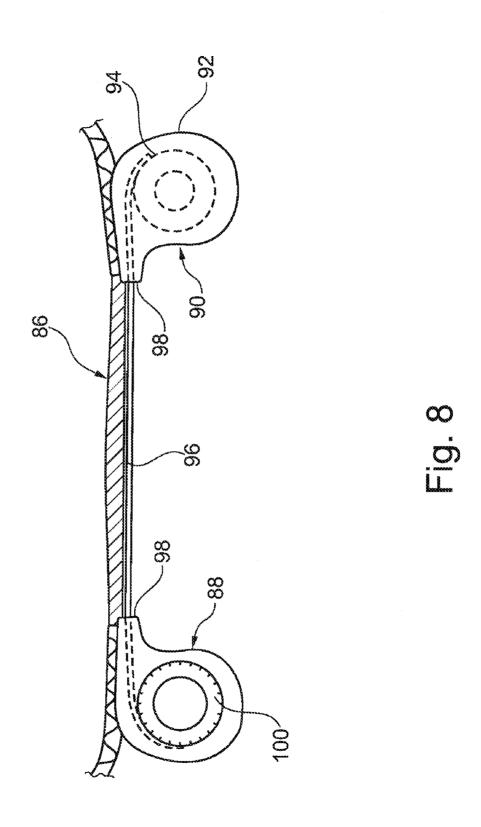


Fig. 7

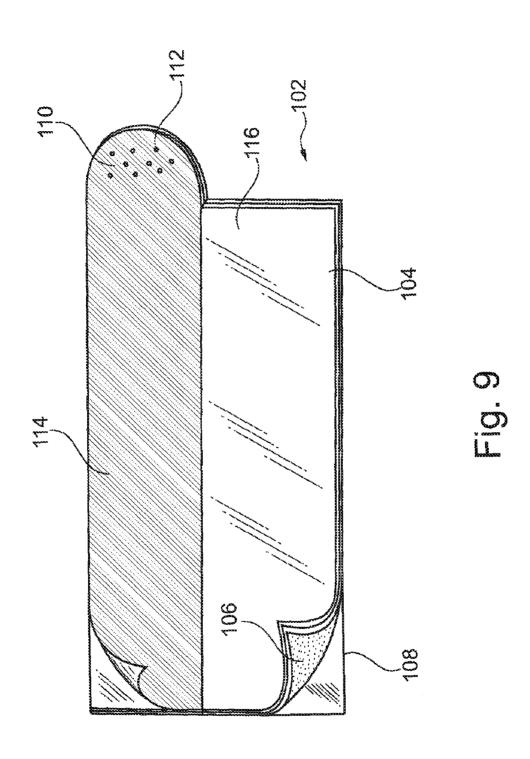
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FACE AND EYE COVERING DEVICE

This application claims the benefit of U.S. Provisional Patent Application No. 60/479,652, filed Jun. 19, 2003.

BACKGROUND

The invention relates generally to protective coverings for the face and eyes.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention, reference is now made to the following descriptions

FIG. 1 is a front elevational view of a face and eye covering device, constructed in accordance with the invention;

FIG. 2 is a side elevational view of an eye shield of the device of FIG. 1;

FIG. 3 is a front elevational view of a shield protector layer of the eye shield of FIG. 2, shown with a pull tab having a textured surface:

FIG. 4 is a cross-sectional view of a portion of the eye shield of FIG. 2;

FIG. 5 is front elevational view of a another embodiment of a face and eye covering device, constructed in accordance with the invention:

FIG. 6 is a front elevational view of an eye shield of the face and eye covering device of FIG. 5;

FIG. 7 is a front elevational view of still another embodiment of a face and eye covering device, constructed in accordance with the invention;

FIG. 8 is a plan view of a protective film reel assembly for a shield of the device of FIG. 7; and

FIG. 9 is a top perspective view of a partially tinted shield protector assembly, shown with a corner of a release liner of the shield protector assembly and an upper tinted film layer partially peeled away.

DETAILED DESCRIPTION

Referring to FIG. 1, a protective face covering device 10 is shown. The device 10 includes a face mask 12 for covering the mouth and face. The face mask 12 may be configured for 45 covering a portion of the wearer's cheeks and chin, as well. The face mask 12 may be the same or similar to those used in surgical or medical environments or in clean room or other sterile environments. Additionally, the face mask 12 may be that such as used in industrial or non-medical applications or 50 environments for preventing the inhalation of dust, debris or other airborne particles.

The face mask 12 may be air permeable to facilitate breathing when worn over the wearer's nose or mouth. The face mask 12 may be formed from woven or non-woven fiber 55 material that is air permeable to allow the passage of air therethrough. It may be in the form of a flexible fabric or paper material, which may be a single or multi-layer material. The mask 12 may also be formed with several overlapping or pleated layers of the flexible fabric or paper material. The face mask 12 may also be formed from a generally rigid material and formed into a suitable shape configured for covering the mouth and nose, such as a cup or cone shape. The mask 12 may constitute a filter or be provided with a filter portion (not shown) to prevent the passage of bacteria through the mask 65 and to prevent or reduce fogging, as is described in U.S. Pat. No. 4,419,993, which is herein incorporated by reference. A

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darkened area or strip 13 may be provided on the mask 12 to reduce glare from overhead light.

Securing devices 14 may be coupled to the mask 12 for securing the device 10 to the face of the wearer. The securing devices 14 may be in the form of straps that are tied about the user's head. Alternatively, the devices may be elastic loops, straps or other members that loop over or secure to the wearer's ears or wrap about the wearer's head. Other securing devices that are known to those skilled in the art may also be

In the embodiment shown in FIG. 1, a neck flap 16 is coupled to the mask 12. The neck flap 16 may be formed from a flexible material that extends downward from the mask 12 taken in conjunction with the accompanying figures, in 15 when worn, and may be tucked into the wearer's shirt or clothing. In certain embodiments, the neck flap 16 may not be present or may be eliminated.

> An eye shield 17 of the device 10 is coupled to the mask 12. The shield 17 includes a lens 18 that may be permanently or removably coupled to the mask 12. As shown in FIG. 1, the lens 18 may be coupled to the mask 12 along the lower edge of the lens 18. In the embodiment shown, a lower extending portion 19 extends downward and overlaps a portion of the mask 12. The lower portion 19 may be coupled to the material of the mask through various means, such as ultrasonic welding, thermal bonding, permanent and repositionable adhesives, stapling, riveting, stitching, hook and loop fasteners (eg. Velcro®), snaps, slots and pegs, etc.

The lens 18 may be a relatively thin sheet of liquid impervious material with all or a portion of the sheet being transparent. The lens may be of a polymeric material (eg. polyester, Mylar, etc.) and be relatively flexible, particular those of lower thickness, so that it may be easily bent, manipulated or otherwise flexed to facilitate creaseless wrapping or curving of the lens 18 around the wearer's head or face. The sheet may have a sufficient stiffness or rigidity, however, so that it stands upright without folding under its own weight and be of sufficient thickness so that it may serve as a protective barrier for shielding the eyes from flying particles or liquid spray or droplets. The lens 18 may be of varying thickness. A suitable range for the thickness of the lens 18 is from about 3 mils to 50 mils, more particularly from about 3 mils to about 10 mils, and still more particularly from about 4 mils to about 7 mils.

The lens 18 may be of a variety of configurations and may be configured to extend across both the wearer's eyes, as well as to either side the wearer's head and forehead. As shown in FIG. 1, the lens has a central eye shield portion 20 that extends across the eyes of the wearer. Opposite side portions 22 extend from either side of the eye shield portion 20. The lens 18 may be provided with creases or bends 24, as shown, so that side portions 22 wrap around either side of the wearer's head. In certain embodiments, a nose cutout (not shown), which may also be provided with or without a separate nose piece (not shown), may be provided to facilitate placing of the device 10 on the wearer's face. An example of such a mask and eye shield combination is described in U.S. Pat. No. 6,026,511, which is herein incorporated by reference.

The lens 18 may also be provided with loops or straps (not shown) or other attachment devices, in addition to those of the mask 12, to facilitate attachment of the shield 17 to the wearer's head. A grasping portion or tab 25 may be provided with the lens. The portion 25 may be formed from a continuous and projecting portion of the lens 18.

The lens 18 may be treated or coated with anti-fog and anti-glare coatings and also be tinted or shaded (eg. amber, smoke, etc.). Examples of commercially available material

US 7,540,039 B2

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60 may be similar to the shield protector 24 of the device 10 and include one or more shield protector layers 62 releasably coupled to the substrate 48 or an adjacent layer 62. A grasping portion or pull tab 64, which may have a cutout 65 or textured surface, may also be provided. A grasping portion or the side portion 52 may also be provided with a cutout or textured surface, such as the surface 66 to facilitate removal of the layers from the upper portion 50 of the substrate 48.

All or a portion of the lower face mask portion 58 of the substrate 48 may be provided with a lower shield protector 68, 10 which is separate from the shield protector 60. Alternatively, a single shield protector may be employed that covers both the upper portion 50 and lower portion 58 of the substrate 48. The lower shield protector 68 may be formed from one or lower portion 58 of the substrate 48 or an adjacent layer 70. A grasping portion or pull tab 72, which may have a cutout 74 or textured surface, may also be provided. Since the lower portion 58 and shield protector 68 do not cover the eyes, these areas may lack optical transparency, if desired.

In use, the device 40 is positioned on the wearer's face. As splatters or other debris accumulate on the surface of either of the shield protectors 60, 68, the protective layers 62, 70 may be sequentially removed one at a time to clear the shield portions 56 and 58, respectively.

Referring to FIG. 7, another embodiment of a face and eye covering device 80 is shown. The device 80 includes a hood 82 that may be formed of a woven or non-woven fiber material, such as flexible cloth or paper material. The hood 82 may also be formed of other materials, which may or may not be 30 permeable to air. The hood 82 fits over the wearer's head and neck and constitutes a face cover. An opening 84 is formed in the hood and a face shield 86 is coupled to the hood 82 and positioned within the opening to thereby close off the opening from the same or similar materials as the shield and lenses previously described. All or a portion of the shield 86 may be optically transparent. The shield 86 may be flexible but have some degree of stiffness or rigidity to prevent it from collapsing, bending or folding during normal use of the device 80.

Coupled to the hood 82 and positioned at either side of the opening 84 are opposite reel assemblies 88, 90. Each reel assembly 88, 90 may include a housing 92 that may be permanently or removably coupled to the hood 82 by various means such as ultrasonic welding, thermal bonding, perma- 45 nent and repositionable adhesives or glues, stapling, riveting, stitching, hook and loop fasteners (eg. Velcro®), snaps, slots and pegs, etc.

A film reel 94 for storing a continuous length of protective film 96 is housed within each housing 92. The film reels 94 are 50 rotatably coupled to the housing 92 of each reel assembly 88, 90. As shown, the reel assembly 90 is a film feed assembly with a length of unused film being stored on the reel 94 of assembly 90. The film 96 may be the same or similar to the described, and may be optically transparent to allow visual perception therethrough. The film 96 passes through openings 98 formed in each of the housings 92 of the assemblies 88, 90 and is oriented so that it extends across and covers all or a portion of the shield 86.

The reel assembly 88 is provided with a dial 100 or other advancement mechanism for advancing the film 96 onto the reel 94 of assembly 88. A similar advancement mechanism (not shown) may be provided on reel assembly 90, if desired. One type of advancement mechanism that may be used is that 65 described in U.S. Pat. No. 4,428,081, which is herein incorporated by reference.

In use, the device 80 is positioned on the wearer's head so that the shield 86 is positioned generally over the wearer's face, with the hood 82 covering the wearer's head and neck. Initially, a clean area of the film 96 is positioned over the shield 86. As the film 96 becomes splattered or covered with debris so that the wearer's vision is obscured, the film may be advanced using the advancement mechanism 100 so that the reel 94 of assembly 88 takes up and stores the soiled film within the housing 92. A fresh or clean length of film is simultaneously advanced from assembly 90 and over the shield 86. This is repeated as necessary.

In an alternate embodiment of the device 100, the reel assembly may be eliminated and one or more individual protective sheets or layers, which may include a grasping more shield protector layers 70 releasably coupled to the 15 portion or pull tab, may be releasably coupled to the shield 86 and removed in a similar manner as described with respect to the embodiments of FIGS. 1-6.

> Referring to FIG. 9, a partially tinted shield protector assembly 102 that may be applied to an existing mask and shield combination of the type having a lens or transparent shield coupled to a mask, such as those previously described, is shown. The assembly 102 includes one or more shield protector film layers 104, each having a layer of releasable, pressure sensitive adhesive 106 applied to one side that may 25 releasably couple adjacent layers 104 to one another. In the embodiment shown, the film layers 104 with the applied adhesive are optically clear. The film layers 104 and adhesive 106 may be the same or similar to that of the previously discussed embodiments. A removable release liner 108 may be applied to the adhesive of the bottom or lower layer to protect the adhesive of the bottom film layer 104.

Each film layer 104 may have a projecting grasping portion or pull tab 110 having a textured surface 112.

In the embodiment shown, the uppermost film layer 104 is 84. The shield 86 may be of varying thickness and formed 35 partially tinted (smoke, amber, etc.) generally across the width of the upper half 114 of the film layer. The lower half 116 of the uppermost film layer 104 may be non-tinted.

In use, the shield protector assembly 102 may be applied to the lens of a preexisting mask and shield combination. The protector assembly 102 may be configured and sized so that it may be applied to most existing mask and shield combinations. If necessary, the assembly 102 may also be cut to size or shape by the user using a scissors, razor or other commonly used cutting tool for fitting on any existing shields. The appropriately sized assembly 102 with the liner 108 removed may then be applied to the outer surface of the lens of the mask and shield. This is done by removing the release liner 108 of the bottom layer 104 to expose the adhesive 106 thereon. The layers 104 are then positioned on the lens of the mask and shield, with the adhesive layer 106 on the bottom layer 104 releasably coupling the assembly 102 to the outer surface of

The assembly 102 has particular application for use in laser surgery operations or applications where there is a need for material forming the protective layers 27, previously 55 initially providing eye protection from bright light. Thus, during such operations, the wearer may look through the upper tinted portion to protect the wearer's eyes from laser or other bright light. The wearer may also look through the non-tinted lower portion 116, tilting or adjusting the orientation of their head if necessary, to see more clearly without the tinting. Upon completion of the activity where protection from bright light is necessary, the wearer or an assistant may remove the uppermost tinted layer 104 by pulling the pull tab 110 and peeling away the uppermost layer 104 to expose the remaining layers 104 or lens of the mask. The underlying layers 104 or lens of the mask and shield combination may be a non-tinted. If desired, however, the underlying layers 104

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may be similarly tinted as well. It should be apparent to those skilled in the art that the partially tinted construction of the assembly 102, as described, could also be employed on the previously described embodiments as well.

The covering devices described herein and components 5 thereof may be disposable and manufactured for a single use or they may be reusable. In certain instances the shield portion may be manufactured and supplied separately from the mask or hood with which it is to be used. The devices may be sterile or sterilizable. Sterilization may be done through ster- 10 ilization techniques that are well known in the art, such as chemical, radiation or heat sterilization methods. The devices may be packaged in a manner to maintain the sterile integrity of the device until they are needed.

While the invention has been shown in only some of its 15 forms, it should be apparent to those skilled in the art that it is not so limited, but is susceptible to various changes and modifications without departing from the scope of the invention. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the 20 scope of the invention.

I claim:

1. A method of forming a face and eye covering device comprising:

laminating at least two layers of flexible material together 25 and then cutting the laminated layers into a desired shape to form an eye shield, the at least two layers of flexible material comprising a lens and at least one lens protector film layer wherein the lens has a greater thickness than any single lens protector film layer, and 30 wherein at least a portion of the at least two layers is transparent to allow visual perception through the at least two layers forming the eye shield, and wherein the at least two laminated layers are releasable so that one of the layers may be selectively removed from the other; 35

directly coupling the eye shield to a face cover along a lower portion of the lens wherein the face cover is configured for covering the nose and mouth of a wearer, the face cover being air permeable to allow the passage of air 40 therethrough to facilitate breathing when worn over the wearer's nose or mouth.

2. The method of claim 1, wherein:

the at least two layers of flexible material are laminated together with a uniform coating of an optically clear 45 adhesive.

3. The method of claim 2, wherein:

the adhesive covers generally the entire surface of the

4. The method of claim 1, wherein:

the at least one lens protector film layer of the at least two layers forming the eye shield has a grasping portion that 8

is provided to facilitate removal of said at least one lens protector film layer of the at least two layers.

5. The meted of claim 4, wherein:

the grasping portion is provided with at least one of a textured surface or cutout to facilitate grasping and removing of said at least one lens protector film layer of the at least two layers.

6. The method of claim 1, wherein:

there are at least three layers of flexible material laminated together that are then cut into the desired shape to form the eye shield wherein the at least three layers of flexible material comprises the lens and at least two lens protector film layers.

7. The method of claim 6, wherein:

the at least two lens protector film layers of the at least three layers has a projecting grasping portion that is provided to facilitate removal of said at least two lens protector film layers of the at least three layers, and wherein the grasping portion is provided with indicia to facilitate distinguishing each of the layers.

8. The method of claim 1, wherein:

all or a portion of at least one of the layers of flexible material is tinted or shaded.

9. The method of claim 1, further comprising:

providing a securing device for the eye shield for securing the eye shield to the head of a wearer.

10. The method of claim 1, wherein:

the lens of the at least two layers of flexible material has a thickness of from about 3 mils to about 50 mils, and the at least one lens protector film layer of the at least two layers of flexible material has a thickness of from about 0.01 to about 3 mils.

11. The method of claim 1, wherein:

the eye shield is sterilized or formed from sterile materials for use in a sterile environment.

12. The method of claim 1, wherein:

the eye shield is disposable.

13. The method of claim 1, wherein:

the eye shield has sufficient flexibility so that the eye shield is contourable.

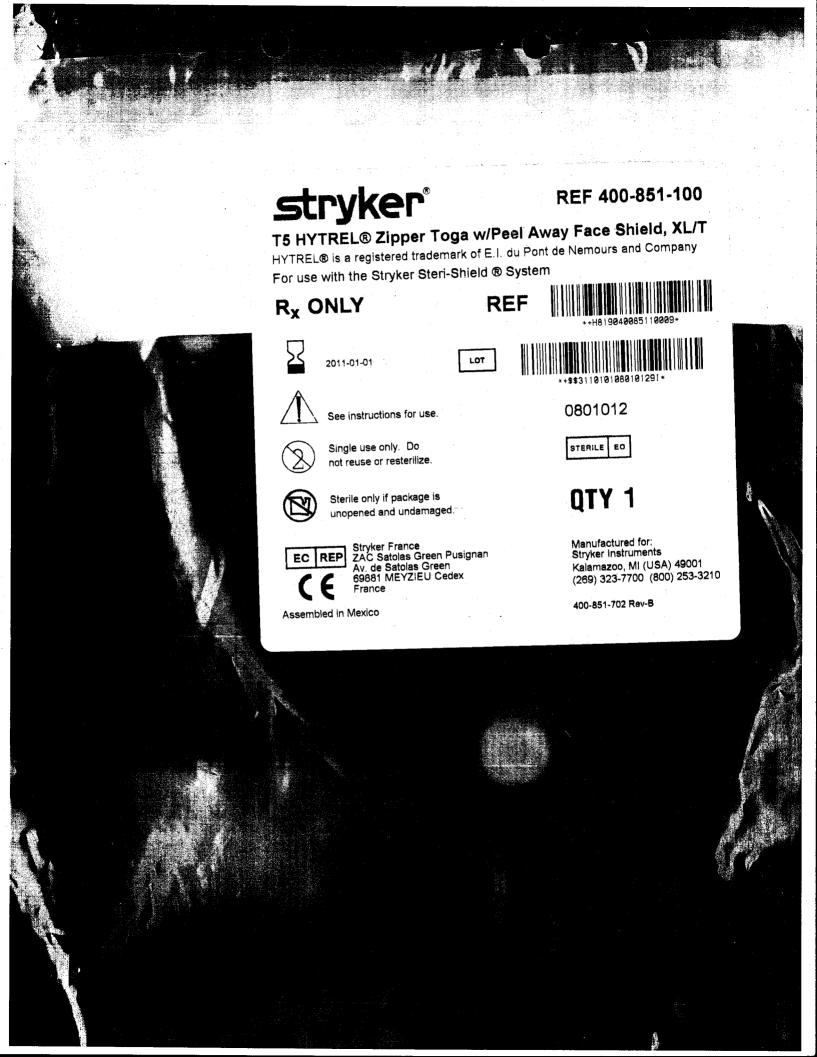
14. The method of claim 1, wherein:

the eye shield is directly coupled to the face cover by at least one of ultrasonic welding, thermal bonding, permanent adhesives, repositionable adhesives, stapling, riveting, stitching, hook and loop fasteners, snap fasteners, slots and pegs.

15. The method of claim 1, wherein:

a portion of the eye shield extends over the face cover.

EXHIBIT 2



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EXHIBIT 3

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EXHIBIT 4

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Case 3:09-cv-01582-M Document 1 Filed 08/26/09 Page 35 of 35 PageID 35 CIVIL COVER SHEET

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